REMARKS

Upon entry of the above amendment, claims 1, 3-10, 12-16, 21, 22, 26, 27, 29-32, 50-87, 89-97 and 101-118 will be pending in the present application (claims 28 and 88 having been cancelled). Claims 4, 27, 81 and 105 have been amended above to remove the terms "biologically active" and "analog." Claim 21 has been amended to add antecedent basis for "said patient" and to include the language "for a time and under conditions effective for the polypeptide to be absorbed through epithelial cells of the lower respiratory tract" as suggested by the Examiner. Claim 56 has been amended to specify those phospholipids recited in claim 1. No new matter has been added.

Attached is a marked-up version of the changes being made by the current amendment.

In the Office Action mailed October 16, 2002, the Examiner indicated that claim 56 was not rejoined because it recited "phospholipid," which the Examiner asserted permitted the presence of any phospholipid, and not just those that are recited in claim 1. Claim 56 has been amended to echo the claim 1 recitation of "a single chain phospholipid, or a double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length". Thus, rejoinder and allowance of claim 56 is respectfully requested. Further, the Examiner indicated that claims 28 and 88 were not rejoined because there was no antecedent basis for "enhancer." These claims have been cancelled, rendering moot the issue of their rejoinder.

Claim 1 is rejected by the Examiner under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 5,518,998 C1, 5,747,445, and 6,165,976. Claim 21 is rejected by the Examiner under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,830,853. Claim 78 is rejected by the Examiner under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,436,902. Claim 102 is rejected by the Examiner under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent

No. 6,004,574. In response, Applicants submit herewith an appropriate terminal disclaimer and the requisite fee, and request withdrawal of the rejection.

Rejection under 35 USC §112 ¶2

The Examiner has rejected claims 4, 22, 26, 27, 29, 30, 32, 50-55, 57-60, 78, 80-87, and 89-97 under 35 USC §112 ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Claims 4, 27, 81 and 105 have been amended to remove references to "biologically active" and "analogs," which were allegedly indefinite. In addition, Claim 21 has been amended to recite "administration of a biologically active polypeptide to a patient," thus providing further antecedent basis for the term "the patient" (it being noted that antecedent basis for this term also appears in claim 1, from which claim 21 depends). Therefore, the Applicants respectfully submit that the rejection under 35 USC §112 ¶2 has been rendered moot and request withdrawal of that rejection.

Applicant asks that all claims be allowed. Enclosed are a check for $660.00 for the Terminal Disclaimer and a $410.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 06275-004001.

Respectfully submitted,

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Version with markings to show changes made

In the claims:

Claims 28 and 88 have been cancelled.

Claims 4, 21, 27, 56, 81, and 105 have been amended as follows:

4. The composition of claim 3, wherein said hormone is vasopressin, [a biologically active analogue of vasopressin,] desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), [a biologically active analogue of] somatostatin, [a biologically active analogue of] gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

21. A method for systemic administration of a biologically active polypeptide to a patient, comprising

providing the composition of claim 1; and

causing said patient to inhale said composition from a dry powder inhaler device for a time and under conditions effective for the polypeptide to be absorbed through epithelial cells of the lower respiratory tract.

27. The method of claim 26, wherein said hormone is vasopressin, [a biologically active analogue of vasopressin,] desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), [a biologically active analogue of] somatostatin, [a biologically active analogue of] gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

56. The method of claim 21, wherein said surfactant compound is an alkyl glycoside, a cyclodextrin or derivative thereof, a single chain phospholipid, or a double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length.

81. The dry powder inhaler device of claim 80, wherein said hormone is vasopressin, [a biologically active analogue of vasopressin,] desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), [a biologically active analogue of] somatostatin, [a biologically active analogue of] gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

105. The composition of claim 104, wherein said hormone is vasopressin, [a biologically active analogue of vasopressin,] desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), [a biologically active analogue of] somatostatin, [a biologically active analogue of] gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.